Wolters Kluwer
Health

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National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted via healthit.gov

Dear Dr. DeSalvo,

On behalf of Wolters Kluwer, I am writing to provide comments on the recently issued draft of the Shared Nationwide Interoperability Roadmap. We commend the Office of the National Coordinator (ONC) for its work in developing the Roadmap and strongly support the goals of advancing the nation towards an interoperable health IT ecosystem that improves patient care, advances research and ultimately helps create a vibrant learning health system.

As way of background, Wolters Kluwer (WK) is a leading global provider of information, business intelligence and point-of-care solutions for the healthcare industry. Key product lines include ProVation® Medical, UpToDate®, Medi-Span®, Lexicomp®, Facts & Comparisons®, Sentri7®, Health Language and Medicom (China). Wolters Kluwer had annual revenues in 2014 of $4.9 billion.

Overall, we support the Interoperability Roadmap (the "Roadmap") and were particularly pleased to see ONC's acknowledgement of the vital role played by structured data in promoting information sharing between providers. However, we were disappointed the Roadmap definition of interoperability was so narrow, focusing exclusively on facility-to-facility sharing of information. Our full comments exploring these and other issues are presented below.

The Definition of "Interoperability"

This first version of the Roadmap focuses exclusively on facility-to-facility interoperability, enabling different electronic medical record systems and platforms to send, receive and view a patient's medical history. To fully achieve the long-term goals of the Roadmap, it is critical we take a more expansive view of the concept of "interoperability." We appreciate the ONC's acknowledgement that other aspects of HIT are necessary to achieve full interoperability, including data quality, documentation and data entry, usability, and workflow. We are disappointed this early version of the Roadmap did not address these aspects as well.

As a modular EHR vendor, Wolters Kluwer Health works with all the major EMR vendors, including Epic, Allscripts, Cerner, McKesson and Meditech. Our products integrate with practically every commercial EMR system, adding state-of-the-art functionality for clinical decision support, provider documentation and patient surveillance. In our experience, ensuring low cost integration of EHR modules and optimizing provider choice of those modules significantly impact on data quality, usability

and workflow. As such, they are just as important as facility-to-facility exchange for achieving system-wide interoperability.

Chief Information Officers routinely choose to install 3rd party modular solutions into their EMR system for a variety of reasons, including superior performance, better design and workflow, and provider preference. In many cases, the choice of a 3rd party module means the preemption of a commercial EMR vendor solution that provides similar functionality. In integrating our solutions with commercial EMR systems, we have encountered a number of unfair business practices which we believe are designed to negatively influence CIO choice of 3rd party modules, including excessive fees and lack of information sharing.

The issue of exorbitant fees charged by vendors to create interfaces in the context of facility-to-facility interoperability has been receiving increasing media attention of late[1], and is cited as a significant barrier to achieving more broad-based data exchange. Less discussed but just as pernicious are the fees charged by many commercial EHR vendors for creating 3rd party module interfaces within their systems. Such fees are often far in excess of the underlying costs of creating the interface, unnecessarily increasing installation costs for providers.

Apart from the amount of the fee an EMR system vendor charges to create an interface with a 3rd party modular solution, there is also the issue of *when* those fees are charged. It has been our experience that an EMR system vendor is more likely to charge an interface fee when the 3rd party module has been chosen to replace the EMR vendor's own solution. For example, there is one EMR vendor in particular that provides an Order Set product, and will charge an excessive integration fee to providers who prefer to install our Provation Order Sets product. Oddly, whenever a provider also wants this same EMR vendor to integrate our Provation Care Plans product, there is no fee charged. This EMR vendor does not have a competing Care Plans product.

Limiting access to the EMR system's data structure is also an artificial roadblock aimed at influencing purchasing decisions. These limits come in many forms, including delays in sharing the information, partial disclosure of relevant information, and overly restrictive contracts that limit the future use of data and hamper 3rd party module maintenance and updates.

The cumulative impacts these unfair practices have on EHR system usability and workflow are pernicious, with negative downstream implications for patient care and safety. As we shared with Jodi Daniel and Karson Mahler this past January 21st, our market research indicates that in considering whether to install a 3rd party module in their commercial EMR system, many CIOs now count ease of integration as a more important factor than the improvement in care or patient safety the 3rd party module may deliver. Ironically, providers using systems containing 'best-of-breed' 3rd party modules report higher clinical performance, but only 10% of CIOs are committed to picking the best modules for their EHR system, regardless of the manufacturer. Hospitals are foregoing clearly beneficial technologies in order to maintain an easier-to-implement "one-system" approach.

[1] http://www.brookings.edu/blogs/techtank/posts/2015/02/24-ehr-records-hostage-yaraghi

Key Principles as the Building Blocks of Interoperability

We support the principles identified by the ONC that will serve as the building blocks for the Interoperability Roadmap. We want to particularly call out the inclusion of two principles, **'maintaining modularity**,' and **'leverage the market'** as particularly important.

As we stated in our recent comments to the draft HIT Strategic Plan, it is important for modular EHR vendors such as Wolters Kluwer to understand what the ONC and CMS are referring to when the term 'modular' is used. In the context of Meaningful Use, the term connotes the type of single- or multi-function software products such as we manufacture that are installed in Electronic Medical Record systems. But recently the term 'modular' has been used to describe mobile medical applications or devices that might be found on a smartphone or other handheld device. We agree the concept of 'modularity' should be a key building block for the Roadmap, but we envision the term encompasses modular EHR products, cloud-based services that work with health information technology as well as the new mobile and hand-held solutions just emerging in the marketplace now. We would appreciate clarification of this issue in the final draft of the Roadmap.

With regard to 'Leveraging the Marketplace,' we reiterate our on-going position expressed in many comment letters sent to the ONC over the years that reliance on the marketplace is one of the most important foundational principles guiding all of the government's work in HIT, not just the Roadmap.

Use of Structured Data for Documentation

On documentation, we strongly applaud the Roadmap's focus on the value of structured data. The form of data being exchanged is critical to promoting greater sharing, and we have found that using structured data is a much more reliable format for facilitating exchange and ensuring that patient data is accurate and actionable for the receiving provider. In considering the advantages of structured data for HIE purposes, we should also not limit our vision to merely a single point-to-point exchange. Patient data elements are links in a chain, sent by one provider, received and utilized by a second provider before being passed along to subsequent members of the care team who may operate in other facilities using different EMR systems.

A case in point is one of our new clinical decision support tools, a hospital-based software module aimed at reducing the incidence and severity of sepsis that will prompt the doctor and nurse with questions about the patient's condition, with the responses recorded as structured data. This data is then processed against a series of CDS rules and appropriate evidence-based advice is then presented back to the clinician. The fruits of this exchange can then be easily exchanged with providers in other care settings.

Common Clinical Data Set

We agree with the common clinical data set outlined in the draft Roadmap, but see this list as a starting point. Going forward, we suggest the addition of diagnostic reports, culture results and surveillance interventions.

Our biggest concern with the common clinical data set is ensuring the integrity of the data. For example, current problem lists in most EHR systems have codified data elements that could meet the

data standards, but we also know that problem lists are usually not kept up to date. The narrative text from dictations often details patient's medical problems in real time after each encounter, but the problem list is seldom updated to be kept in sync with the dictated notes. The ultimate utility of the common clinical data set is heavily dependent on the integrity of the inputted data. This should be reflected in the revised version of the Roadmap.

Incentives to Promote Interoperability

We agree in concept with using Medicare's new alternative payment models to provide incentives for interoperability and health information exchange, but we counsel caution in the application of this approach. In our view, adding additional incentives or mandates largely depends on the pay-for-performance model.

For example, the value of exchanging patient information in an Accountable Care or Bundled Payment arrangement should be self-evident to participating providers. The inclusion in the ACO quality measure set of the requirement that at least 50% of ACO providers be meaningful users of certified technology, coupled with the fact that this measure carries twice the weight of other measures, is probably sufficient to spur interoperability and exchange within that model.

Other models such as the Hospital Readmission penalty program might be candidates for additional incentive. Early research indicates that hospitals that closely coordinate with primary care doctors on the care of recently discharged patients experience fewer unscheduled readmissions.[2] CMS might consider lessening the severity of incurred penalties if a hospital can demonstrate they engaged in health information exchange with a set percentage of primary care providers who provide care for their discharged patients.

And lastly there are the pay-for-performance programs such as the hospital acquired condition (HAC) penalties where the provider's underlying performance (or lack thereof) has little to do with whether they are engaging in health information exchange with other providers outside their facility. It makes little sense to require interoperability from a hospital hoping to avoid or lessen the severity of penalties because their HAC rate is too high.

Participation of Standard Development Organizations (SDO)

We agree that private sector Standard Development Organizations (SDO) such as HL7 and NCPDP should play a prominent role in developing, curating and maintaining the various standards and implementation specifications needed to support interoperability. We actively participate in both organizations and the contributions they have made to date are invaluable. However, we counsel caution in giving too large a role to government entities.

The National Library of Medicine (NLM), for example, has played a useful role in supporting clinical standards such as SNOMED, LOINC and RxNorm, but giving them a leadership role in standards development and curation may be beyond the organization's mission, core competencies and, perhaps most important, budget. We note the NLM did not have sufficient funding to implement the Value Set Authority Center (VSAC) and had to borrow those funds from CMS. The vagaries of government funding should be a cause of great concern in giving entities such as NLM a primary or leadership role in

[2] Journal of Family Practice, Vol 63 No. 2, pages 67-74, February 2014

standards development. In contrast, private sector SDOs have steady streams of funding and are squarely focused on standards development as their core mission.

This isn't to imply that standards development should be left exclusively in the hands of private sector SDOs, many of whom charge exorbitant fees to use their vocabularies and/or make licensing difficult. We believe the development of new standards, vocabularies and value sets should be done with the input and consensus of multiple stakeholders, both public and private, and that the ongoing licensing and use of such standards should be easy and low cost for the end user.

Consolidated Clinical Document Architecture (C-CDA)

We share the ONC's concerns with the implementation issues that have arisen with the Consolidated Clinical Document Architecture (C-CDA) standard. In a study first detailed this past November in the on-line version of JAMIA,[3] the authors conducted a detailed review of 21 C-CDA samples received from different vendors, identifying a total of 615 errors and heterogeneities. While heterogeneities are not as serious as errors, they nevertheless limit the value of these documents for machine-to-machine interoperability.

The authors also conducted automated reviews for syntax and semantics. The syntactical review essentially checked whether the XML documents conformed to the XML schema. Eleven of the 21 documents contained syntax errors, and of these 11, there was an average of 71 errors per document. The semantic review looked at the content of the XML, for example, to see if units were expressed in the prescribed standard format. The average semantic score was 63%, with a range of 23% to 100%. Only 4 of the 21 documents scored above 80% on the semantic assessment.

These results are not surprising. The specification for HL7 C-CDA release 1.1 is 581 pages, so it's not difficult to imagine errors and heterogeneities arising when attempting to produce documents that conform to the specification. The authors suggested some steps that could be taken to improve C-CDA quality, including providing more sample documents, validating codes against some reference, reducing the number of optional data elements, and tracking the quality of these documents as they are used in the real world.

For continuity of care purposes, the C-CDA will probably continue to be an important document for exchanging healthcare information. For other purposes, such as clinical decision support (CDS), other standards such as HL7's FHIR may be more appropriate.

Application Programming Interfaces (API)

We support and acknowledge the need for a standard set of public APIs to facilitate the more rudimentary aspects of health exchange, but counsel caution that public APIs not grow to eclipse or prevent the continued development and use of proprietary APIs. As with standards and value sets, the private sector will always be able to act more quickly and nimbly than government in meeting market needs for new and innovative APIs. True interoperability won't be achieved unless accommodation is made for both public and proprietary interfaces.

[3] http://jamia.oxfordjournals.org/content/21/6/1060

Moving from Document-Centric to Data-Centric Architecture

We agree with the need to transition from document-centric to data-centric information exchange as well as with the use of the Fast Healthcare Interoperability Resources (FHIR) standard as the data model. An important virtue of FHIR is its simplicity. It consists of simple classes and attributes that are straightforward to implement. It will also be important to identify the terminologies and value sets that should be used to populate the data elements in the FHIR model for various use cases. The FHIR profiles for quality, being balloted by HL7 in May 2015, provide an example of how to optimize FHIR for the clinical decision support and clinical quality measurement use cases. We should point out however that in some cases, even with the use of profiles, there is still more than one way to represent something in FHIR. For example, an order for an imaging study might be represented as a DiagnosticOrder, a ProcedureRequest, or a ReferralRequest. Interoperability may be limited if there's no consensus on representations in FHIR. Despite this, we are very supportive of FHIR as the model for health care data exchange.

Interoperability Use Cases Deserving of Priority

Many of the proposed use cases listed rely on the exchange of information between patient and provider or provider and public health agency. Two, in particular, stand out for us and are worthy of being given priority. They are: *data for disease surveillance, immunization tracking and other public health reporting are exchanged automatically* (#27 on the use case list); and *query-based exchange should support impromptu patient visits in all settings* (#29). Both these use cases enable next generation clinical decision support and surveillance, which in turn will result in improved quality of care and better outcomes for patients.

Thank you again for the opportunity to comment. Should you have additional questions, we would be happy to elaborate on any of the issues discussed.

Sincerely,

Joel Arp
Director, Marketing and Commercial Programs
Wolters Kluwer Health-Clinical Solutions